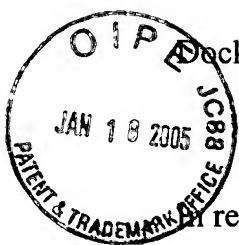


1615 3001



Docket No. 455-019

Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

JEFFREY S. KIEL ET AL.

Serial No.: 10/505,355

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Group Art Unit: 1615

Filed: AUGUST 19, 2004

For: DIPHENHYDRAMINE TANNATE LIQUID AND SEMI-SOLID COMPOSITIONS AND METHODS OF USE

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant discloses to the Examiner under 37 CFR 1.56, and 37 CFR 1.97-1.98, as revised (1135 OG 13) and effective March 16, 1992, the information listed on the attached form PTO/SB/08A, Substitute for form 1449A/PTO. This information may be found to be material to this invention under the current applicable patent law and as interpreted by the US PTO Rules, as cited above. Review and consideration of the listed references/information during substantive examination of this application is respectfully requested.

Applicant specifically emphasizes that this statement, and/or the act of providing copies of these references, is not to be construed as an admission that all or any of the

references are prior art to the specific invention disclosed and claimed.

Also, nothing in this statement is to be construed as a representation that this is the only material information to be found, or the best. It, however, is the only information known to the applicant at this time that is believed to meet the "materiality standard" of the law. If additional qualifying references or other information is discovered in the future, it will be submitted promptly to fulfill applicant's continuing duty of disclosure under 37 CFR 1.56.

Respectfully submitted,

**KING & SCHICKLI, PLLC**



Warren D. Schickli  
Registration No. 31,057

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Lexington, Kentucky 40507  
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CERTIFICATE OF MAILING

I hereby certify that this correspondence  
is being deposited with the United States Postal  
Service as first class mail in an envelope addressed  
to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450,  
Alexandria, VA 22313-1450, on 1-12-05

Date Jan. 12, 2005 S. Williams



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/505,355		
		Filing Date	08/19/2004		
		First Named Inventor	JEFFREY S. KIEL		
		Art Unit	1615		
		Examiner Name			
Sheet		of		Attorney Docket Number	455-019

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)				
	1	us-	6,306,904	10/23/2001	GORDZIEL	
	2	us-	6,117,452	09/12/2000	AHLGREN ET AL.	
	3	us-	5,759,579	06/02/1998	SINGH ET AL.	
	4	us-	5,614,178	03/25/1997	BLOOM ET AL.	
	5	us-	5,599,846	02/04/1997	CHOPDEKAR ET AL.	
	6	us-	5,164,398	11/17/1992	SIMS ET AL.	
	7	us-	5,025,019	06/18/1991	SUNSHINE ET AL.	
	8	us-	4,839,354	06/13/1989	SUNSHINE ET AL.	
	9	us-	4,767,402	08/30/1988	KOST ET AL.	
	10	us-	4,749,723	06/07/1988	SUNSHINE ET AL.	
	11	us-	4,749,722	06/07/1988	SUNSHINE ET AL.	
	12	us-	4,749,721	06/07/1988	SUNSHINE ET AL.	
	13	us-	4,749,711	06/07/1988	SUNSHINE ET AL.	
	14	us-	4,749,697	06/07/1988	SUNSHINE ET AL.	
	15	us-	4,619,934	10/28/1986	SUNSHINE ET AL.	
	16	us-	4,309,989	01/12/1982	FAHIM	
	17	us-	3,282,789	11/01/1966	MARTY ET AL.	
	18	us-	2,950,309	08/23/1960	CAVALLITO	
	19	us-	2,421,714	06/03/1947	RIEVESCHL	
	20	us-	2,397,799	04/02/1946	MARTIN ET AL.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	-Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B (10-01)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
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		Filing Date	08/19/2004		
		First Named Inventor	JEFFREY S. KIEL		
		Group Art Unit	1615		
		Examiner Name			
Sheet		of		Attorney Docket Number	455-019

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	1	CYPRESS PHARMACEUTICAL, INC., "R-Tannic-S A/D," RX Only, Cypress Pharmaceutical, Inc., (Madison, MS), p. 1, 2 (March 1, 2001).	
	2	DSC LABORATORIES, "Phenylephrine Tannate/Pyrimilamine Tannate Suspension," RX Only, DSC Laboratories (Muskegon, MI), p. 1, 2 (Aug. 1, 2001).	
	3	RONALD GOLDBERG, M.D. and FRANKLIN SHUMAN, M.D., "Evaluation of a Prolonged Action Oral Antihistaminic Preparation as Treatment for Allergic Disorders," Clinical Report, Clinical Medicine (Washington), Vol. 72 (No. 9), pp. 1475-1479 (Sept. 1, 1965).	
	4	JOHN WEILER, M.D. ET AL., "Randomized, double-blind, parallel groups, placebo-controlled study of efficacy and safety of Rynatan in the treatment of allergic rhinitis using an acute model," Annals of Allergy, ACAI (Iowa City, IA), Vol. 64 (No. 1), p. 63-67 (Jan. 1, 1990).	
	5	(455-016) U.S. Patent Application No. 10/119,285 filed 04/09/2002: "Process for Preparing Tannate Liquid and Semi-Solid Dosage Forms" (Notice of Allowance has been issued)	
	6	(455-016 CONT) U.S. Patent Application No. 10/921,438 filed 08/19/2004: "Process for Preparing Tannate Liquid and Semi-Solid Dosage Forms"	
	7	(455-017) U.S. Published Patent Application No. US2003/0077321 A1 published on April 24, 2003: "Process for Preparing Tannate Tablet, Capsule or other Solid Dosage Forms"	
	8	(455-020) U.S. Patent Application No. 10/505,347 filed 08/19/2004: "Diphenhydramine Tannate Solid Dose Compositions and Methods of Use"	
	9	(455-021) U.S. Published Patent Application No. US/2004/0234593 published on November 25, 2004: "Diphenhydramine Tannate Compositions and Methods of Use"	
	10	(455-030) U.S. Patent Application No. 10/799,302 filed 03/12/2004: "Single Tank Process For Preparing Tannate Liquid and Semi-Solid Dosage Forms"	

Examiner Signature		Date Considered	
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